

REMARKS/ARGUMENTS

Following entry of the present Response and Amendment, claims 1-66, and 80-128 remain in this application, with claims 1, 37, 57, and 128 being written in independent format.

In the Office Action dated February 23, 2006 (the "Office Action"), claims 117-119 were rejected as allegedly being indefinite under 35 U.S.C. § 112, second paragraph.

With respect to prior art, the Office Action rejected claims 57-58, 62-62, 120, 126, and 127 under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 6,422,240 to Levitsky et al. (henceforth "Levitsky") in view of U.S. Patent No. 6,439,234 to Curti et al. (henceforth "Curti"). Further, the Office Action rejected claim 59 under 35 U.S.C. § 103(a) as allegedly being unpatentable over both Levitsky and Curti in further view of U.S. Patent No. 5,535,739 to Rapaport et al. (henceforth "Rapaport"). Additionally, the Office Action rejected claims 60-61 under 35 U.S.C. § 103(a) as allegedly being unpatentable over both Levitsky and Curti in further view of U.S. Patent No. 6,467,477 to Frank et al. (henceforth "Frank"). Finally, claims 117-119 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over both Levitsky and Curti in further view of U.S. Patent No. 5,046,491 to Derrick (henceforth "Derrick").

Claims 1-5, 10-14, 16-56, 64-66, 80-115 and 128 were allowed, and claims 121-125 were indicated as being directed to allowable subject matter, but were objected to in the Office Action only on the basis of being dependent claims referring to rejected independent claims.

In the present Response and Amendment, claims 37, 57, 84, 86, 117, 119, and 128 have been amended. New dependant claims 129-131 have been introduced for examination upon the merits. These amendments to the claims have been introduced to clarify the subject matter of the present invention, and to place the present application in better condition for allowance.

Applicant submits that the above-requested amendments do not add prohibited new subject matter, and respectfully requests reconsideration of the merits of the present application in accordance with these amendments and the following remarks.

Claim Rejections

Each of the grounds for claim rejections is addressed below.

35 U.S.C. § 112, second paragraph

Applicant submits that all claim rejections under section 112 have been obviated by the amendments to the claims 117 and 119 made herein. Specifically, it is believed that all presently pending claims have proper antecedent basis for all limitations and that all dependent claims recite the proper dependency.

Reconsideration and removal of this rejection is thus respectfully requested.

35 U.S.C. § 103(a) – applying Levitsky and Curti

Insofar as these two references serve as the underlying grounds for rejection with respect to all of the claims as presently amended, Applicant respectfully traverses as follows.

First, Applicant notes that independent claims 37 and 128 (which were indicated as being allowed) have herein been amended by the Applicant. In particular, independent claim 37 was amended so that the claim consistently uses the term “individually” throughout the claim for sake of clarity, while independent claim 128 was amended to recite the presence of an analyzer system comprising one or more analyzer devices (such as capnographs, as defined in new dependent claim 129). These changes to the claims places them in better form, and does not affect the allowability of these claims over the prior art for the reasons set forth in Applicant’s various previous remarks with respect to these claims. Applicant requests an indication of allowance of these claims as amended, and appropriate consideration of new dependent claims 129-131 in light of Applicant’s prior remarks.

With regard to the obviousness rejections in the Office Action based upon this art, independent claim 57 as previously presented was rejected with the Office Action continuing to allege that Levitsky teaches placing an oronasal device having the structure specifically recited by claim 57 in an area between a nose and mouth of a person where the cannula device has portions for collecting expired gases from each nostril and from the mouth. The Office Action thereafter purportedly combines Levitsky with Curti to add the limitation that

the device also enables the determining of whether the person is inhaling or exhaling and delivering an increased flow of inspired gas to the person during the inhalation phase.

First, as noted many times by Applicant, Levitsky (as admitted by the Office Action) does not teach detecting when a person is inhaling or exhaling and delivering an increased flow of inspired gas to the person during the inhalation phase. To overcome this problem, the Office Action alleges that Curti can be combined with Levitsky to suggest this combination to one skilled in the art. Again, Applicant submits that this combination is wholly inadequate to render the claimed invention obvious.

Levitsky describes a device that includes a Y-shaped junction located between the nose and mouth where the tubes of the two nasal prongs and of an oral prong meet with a collection tube. The collection tube thereafter carries the gas to a downstream analyzer. An oxygen delivery tube, adapted to lie across the upper lip of the patient, is also disclosed. This delivery tube has two holes oriented below the nose of the patient intended to direct oxygen flow upward through a screen and to the nostrils of the patient for inhalation. As admitted in the Office Action, Levitsky does not address modulating the flow of delivered gas in any way.

Curti describes a device that has a first nasal prong for collecting gases only, and a second nasal prong (intended for insertion in the other nostril) for delivering gases only. This device clearly does not meet the structural limitations recited in claim 57, but only teaches one way to simultaneously deliver oxygen to be inhaled while sampling expired gases for analysis. While this reference generally may describe the usefulness of simultaneous oxygen delivery and expired gas monitoring, it does not teach or suggest to one skilled in the art to modify the device and methods taught in Levitsky to produce Applicant's claimed invention – one way of achieving a result does not render obvious all other ways of achieving that result. “When prior art references require selective combination by the court to render obvious a subsequent invention there must be some reason for the combination other than the hindsight gleaned from the invention itself.” *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 732 F.2d 1572, 1577 & n.4, 221 USPQ 929, 933 & n. 4 (Fed. Cir. 1984). There must be “something in the prior art to suggest the desirability, and thus the obviousness, of making the combination.” *Lindemann Maschinenfabrik GmbH v. American Hoist and Derrick Co.*, 730 F.2d 1452, 1462, 221 USPQ 481, 488 (Fed. Cir. 1984). Levitsky and Curti are two very

different devices that operate on different and, according to the references themselves, mutually exclusive principles. No motivation is contained in either for one skilled in the art to consider their combination. As explained many times by Applicant, an accurate and complete reading of Levitsky and Curti will produce no basis for combining their teachings, but instead will find reasons contradicting such a combination. Prior art references must be considered in their entirety, including those portions that would teach away from the claimed invention. *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1552 (Fed. Cir. 1983), *cert. denied*, 105 S. Ct. 172 (1984). The Office Action's selective reading of these two references to bolster its rationale for combining them is improper. Thus, claim 57 and its dependent claims is allowable for this reason.

Second, independent claim 57 is allowable over the combined teachings of both Levitsky and Curti because neither reference discloses, teaches, or suggest "a plurality of fluid outlet holes in said device body, said holes being located immediately about the base of each said portion that extends toward said nostrils so as to partially surround each said nostril portion."

The Merriam-Webster free online dictionary (accessible via the Internet at <http://www.m-w.com>) defines the verb "surround" as follows:

1 a (1) : to enclose on all sides : ENVELOP <the crowd surrounded her>
(2) : to enclose so as to cut off communication or retreat : INVEST b : to form or be a member of the entourage of <flatterers who surround the king> c : to constitute part of the environment of <surrounded by poverty>
d : to extend around the margin or edge of : ENCIRCLE <a wall surrounds the old city>

A copy of a printout of this online definition is attached in the Appendix at the end of this paper. The definition of "surround" presented in this dictionary is the plain meaning of this term, and the manner in which one skilled in the art would understand the term after reading Applicant's specification would clearly comport with the plain meaning. Namely, one skilled in the art would construe "surround" to mean to enclose on all sides, to envelop, or to extend

around.

Similarly, the Merriam-Webster online dictionary defines the adverb partially as follows:

1 *archaic* : in a biased manner : with partiality

2 : to some extent : in some degree

A copy of a printout showing this online definition is likewise contain in the Appendix attached hereto. The modern definition of “partially” presented in this dictionary, “to some extent or in some degree” again reflects the plain meaning of this term.

When Applicant’s specification and figures are properly considered, one skilled in the art would understand the compound terms “to partially surround” as meaning “to enclose, envelop, or extend around to some extent or degree.”

The Office Action, however, makes the specious argument that Levitsky depicts in FIG. 6a a plurality of fluid outlet holes (i.e., holes 88) that partially surround fluid inlets (i.e., nasal prongs 78). Levitsky discloses no such thing. Rather, Levitsky discloses an “oxygen tube 86” that lies across the upper lip of the patient to direct oxygen flow out of “two holes 88” (one hole for each nostril) into the nostrils of the patient. See Levitsky at col. 9, lines 5-15 and FIG. 6a. Applicant admits that Levitsky discloses two holes that output oxygen, and understands that two of any type of thing forms “a plurality” of those things. However, it cannot be concluded without completely ignoring the confines of the claim language used by Applicant that Levitsky shows a plurality of holes that are “located immediately about the base of each said portion that extends toward said nostrils so as to partially surround each said nostril portion.”

In Applicant’s claim, the plurality of holes is located immediately about the base of each nostril portion, and also partially surrounds each portion (i.e., the plurality of holes encloses, envelops, or extends around each portion to some extent or degree). Levitsky’s two holes, in contrast, are located on an oxygen tube that runs essentially tangential to the nasal prongs 78. A single hole 88 is located on the oxygen tube near each nasal prong 78. Levitsky’s two solitary holes, spaced apart with one located near each nasal prong, cannot be

considered to form a plurality of holes that is located immediately about the base of either one of the nasal prongs, let alone each portion as recited by Applicant. Further, in no way would one skilled in the art consider Levitsky to describe a device having a plurality of fluid outlet holes that partially surround anything. The holes 88 do not form any pattern that would enclose, envelop, or extend around either nasal prong 78 to any extent or degree, let alone partially surround each portion as claimed by Applicant. While “the PTO must give claims their broadest reasonable interpretation, this interpretation must be consistent with the one that those skilled in the art would reach.” *In re Cortright*, 165 F.3d 1353 at 1358 (Fed. Cir. 1999) (citing *In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997)). The Examiner cannot bootstrap a rejection by simply giving claim limitations, such as Applicant’s “immediately about the base ... so as to partially surround,” a meaning that is so broad that it conflicts with the meaning that one skilled in the art would give the terms. *Id.*

The prior art teaches, if anything, a single hole located near each nasal prong. Those holes cannot therefore be “located immediately about the base of each said portion that extends toward said nostrils so as to partially surround each said portion.” Applicant’s specific structural limitations as recited in claim 57 therefore render this claim patentable over the combined teachings of Levitsky and Curti.

Appropriate reconsideration of claim 57 and all claims dependent therefrom is respectfully requested in light of the above remarks.

35 U.S.C. § 103(a) – applying Levitsky, Curti and Derrick

Claims 117-119 were rejected by the Office Action under 35 U.S.C. § 103(a) as allegedly being unpatentable over the combination of Levitsky and Curti as further modified in light of Derrick. Insofar as this grounds for rejection applies to these claims as presently amended, Applicant respectfully traverses.

The Office Action contends that Derrick in FIG. 1 and FIG. 2 teaches a device that has “fluid outlet holes arranged in a concentric arc” and that this disclosure renders obvious Applicant’s limitations as recited in claims 117-119. This, Again, is a mischaracterization of the prior art. Specifically, Derrick discloses in FIG. 3 a inhalant gas source, but nowhere describes where that gas exits. The holes apparently referenced by the Examiner in FIG. 1

and FIG. 2 of Derrick are not identified by reference numeral in that reference's drawings and, to Applicant's knowledge, are also not described in the specification. Thus, Derrick cannot be accurately described as teaching anything with respect to the number, location, or orientation of fluid outlet holes, and the Office Action has no basis whatsoever for concluding that where fluids are outputted on the Derrick device.

Further, even if the holes on the smile shaped member in FIG. 1 were fluid outlet holes, it is clear that such holes are not located "immediately about the base of each said portion that extends toward said nostrils so as to partially surround each said nostril portion" as recited in claim 57. The holes in Derrick appear to make a "smile" shape centered on the nose of the patient. That smile shape clearly is depicted as extending far away from the base of the nostril prongs 20. These holes therefore cannot be considered to be "arranged in an arc around the base of each nostril portion" (i.e., prongs 20) "to diffuse supplied gas into each nostril" as recited in claim 117. No arc of fluid outlet holes is formed around the base of each nostril portion, as claimed, making all of claims 117-119 allowable over the asserted prior art.

Additionally, claim 119 adds the limitation that the "plurality of holes are arranged in a substantially concentric pattern around each said nostril portion." Again, relying upon the Merriam-Webster online dictionary definition for the adjective "concentric" (a printout copy for this online definition is contained in the Appendix), namely:

- 1 : having a common center <concentric circles>
- 2 : having a common axis : COAXIAL

it becomes clear that Applicant's term "concentric" is being given an improper meaning in order to bootstrap the Office Action's prior art arguments. The definition of "concentric" requires a common axis or center, while Derrick discloses, if anything, an arc of holes that is centered on the point of the nose of the patient. This is not concentric with (i.e., sharing a center or axis with) either of the two nostril portions, let alone each nostril portion as claimed.

Appropriate reconsideration is thus requested.

New Claims

Applicant has submitted herewith new dependent claims 129-131, which depend from previously allowed independent claim 128. These claims recite features of the invention that have been previously discussed. For example, claims 130 and 131 recite features of the fluid outlet holes that, as explained immediately above, distinguish from the prior art as defined by Levitsky, Curti and Derrick.

Allowable Claims

Applicant again thanks the Examiner for the indication of allowable subject matter in this application and notes that several amendments have been made to these claims to retain make minor corrections. Applicant believes that these amendments should not impact the current allowability of these claims over the prior art.

Request for Examiner Interview

If the claims are not considered to be immediately allowable, Applicant requests that the Examiner grant the courtesy of a telephonic interview once the Examiner has had the chance to sufficiently review the contents of this paper. Applicant believes that such will most efficiently result in the claims being prepared for immediate allowance as there are clear differences between the embodiments of Applicant's invention and the cited prior art. Thus, the Examiner is respectfully requested to contact the undersigned representative to schedule the telephone interview in the coming weeks before the mailing of any subsequent Office Actions.

Application No. 09/878,922
Response and Amendment dated May 23, 2006
Reply to Office Action of February 23, 2006

Conclusion

In view of the foregoing, the Applicant respectfully requests that the Examiner consider the above-noted Response and Amendment when the claims are reconsidered on their merits. A timely allowance of the pending claims is requested.

The number of claims have been increased through this Amendment, and a check in an amount believed due for additional claims fees has been submitted herewith. If, however, Applicant's calculations in this regard are wrong, please charge any necessary fees or credit any overpayments to Deposit Account No. 50-1349. Additionally, if there are any other fees due in connection with the filing of this Response and Amendment that are not covered by the enclosed check please charge those other fees to Deposit Account No. 50-1349.

The Examiner is invited to contact Applicant's undersigned representative to expedite prosecution at the below telephone numbers.

Respectfully submitted,

Dated: May 23, 2006

HOGAN & HARTSON LLP
555 13th Street, N.W.
Washington, D.C. 20004
Telephone: 202-637-5600
Facsimile: 202-637-5910

Customer No. 24633

By: 

Celine Jimenez Crowson
Registration No. 40,357
Tel : 202-637-5703

Kevin G. Shaw
Registration No. 43,110
Tel : 202-637-6466

Application No. 09/878,922
Response and Amendment dated May 23, 2006
Reply to Office Action of February 23, 2006

A P P E N D I X